AMERICAN VETERINARY MEDICAL ASSOCIATION
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September 3, 1998

Docket No. 98N-0339
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 98N-0339
FDA Stakeholders Meeting
Food and Drug Administration Modernization Act

Dear Sir or Madam:

In addition to its presence at the August 19, 1998 stakeholders meeting, the American Veterinary Medical Association wishes to comment in writing on the questions posed by the FDA as part of the Food and Drug Administration Modernization Act. The objective of the AVMA is to advance the science and art of veterinary medicine, including its relationship to public health, biological science, and agriculture. The Association provides a forum for the discussion of issues of importance to the veterinary profession, and for the development of official positions. The Association is the authorized voice for the profession in presenting its views to government, academia, agriculture, pet owners, the media, and other concerned publics.

The questions posed were both general to the FDA and specific to the Center for Veterinary Medicine. Our comments appear in the order the questions were asked.

In the first general question the FDA asks what it can do to improve its explanation of the Agency's submission review processes, and make explanations more available to various parties?

- At times practicing veterinarians have an interest in finding a way to bring an idea for a drug to market. Also, practitioners want to be knowledgeable of the general types of tests that drugs are subjected to as part of the approval process. General guidance on the animal drug approval process could be a resource to practicing veterinarians. While guidance exists in the form of regulations, the FD&C Act, and CVM staff guidance, the agency could work with the *Journal of the AVMA* staff to feature this information in a reader friendly manner.

- The intricacies of the submission review process are primarily the concern of the animal drug sponsors. However, veterinarians are highly concerned with the process' impact on drug availability. Clear communication and transparency of the process is paramount. Implementation of the letter and spirit of the Animal Drug Availability Act, particularly with respect to efficacy testing requirements, binding pre-submission conferences, and minor use/minor species approvals must be uniformly welcomed by the Center.

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The second question seeks to determine how the Agency can maximize the availability and clarity of information concerning new products.

- Once the FDA has approved an animal drug, announcements of the new product (apart from the Federal Register announcement) should be at the discretion of the animal drug sponsor, allowing them to launch their new product in the fashion they see fit.

- Information on the actual use of newly approved drugs can best be communicated, when applicable, through the flexible labeling concept. This gives the practitioner a low and high dose within which to work and maximizes the number of diseases possibly treated with that product.

- Sometimes adverse effects that were not present during the drug approval process arise shortly after introduction of a new drug to the market place. Practitioners would appreciate improved communication of observations that result in a requirement or a label change. Such timely information helps to ensure the quality of medical care delivered by the veterinarian. The Center could provide this information in the *CVM Update* and the information could then be picked up in publications including the *Journal of the AVMA*.

The third question is compound and the Association will respond to the second part which asks how the FDA can best establish and sustain an effective, timely, and science-based postmarketing surveillance system for reporting, monitoring, evaluating, and correcting problems associated with use/consumption of FDA-regulated products.

We have several comments on the surveillance and compliance issues of reporting, monitoring, evaluating, and correcting problems.

- Passive reporting of potential adverse reactions by practitioners may be heightened by promotion of the available reporting options. We are pleased to note that the process of adverse drug experience reporting was reviewed in an article written by CVM staff that appeared in the July 15, 1998 issue of the *Journal of the AVMA*.

- With respect to use of FDA-regulated products, the AVMA desires ongoing and enhanced support from the Center to answer questions related to extralabel drug use by veterinarians. Generally these questions involve the agency's evaluation of a situation and interpretation of regulatory policy.

- With regard to correcting problems associated with the use of FDA regulated products, the AVMA mentions an area of concern: the illegal distribution of prescription drugs to end users without authorization from a veterinarian involved in a veterinarian-client-patient relationship. The AVMA would like to see an enforcement presence on this issue.

- Given the recent focus on postmarketing surveillance of antimicrobials used to treat food animals, the AVMA feels compelled to state that while we enthusiastically support improved antimicrobial susceptibility monitoring programs, the goal must always be the retrieval of useful and scientifically sound information with the recognition that the cost must not become so prohibitive so as to adversely affect drug availability. In addition we urge for transparent science-based discussions with stakeholders as the agency embarks upon evaluating the results obtained from expanding monitoring programs and determining any corrective actions. We look forward to active participation in upcoming meetings of this nature that the Center has planned.

Question # 4 asks what approach the FDA should use to ensure an appropriate scientific infrastructure with continued access to scientific and technical expertise needed to meet its statutory obligations and strengthen its science-based decision-making process.

- In this era of increasingly complex scientific issues it is imperative that the Center has timely access to the best scientific expertise available. This is the foundation of good decision making. The AVMA would support increased funding for the CVM and the ability to contract with scientific experts.

Question # 5 asks what the FDA should do to adequately meet the demands that are beginning to burden the application review process, especially for non-user fee products, so that it can meet its statutory obligations to achieve timely product reviews?

- The AVMA would urge all members of the CVM to embrace the letter and spirit of the Animal Drug Availability Act. This includes productive presubmission conferences and reduced emphasis of the requirements for efficacy in keeping with the provisions of the ADAA. Again, science based decision making and transparency must prevail. The AVMA awaits the proposed rule regarding minor species and minor uses drug approvals.

- Pertaining to user fees, in 1993 the AVMA approved a position statement that reads, "The AVMA supports user fees for new animal drug applications only if such fees are directed toward enhanced review and approval of animal drug products." It must be remembered, however, that the costs of user fees will ultimately be recovered in the purchase price of the drug. For the livestock and poultry industries, higher costs of drugs can offset the benefit of improved drug availability when producers can not afford to use the drugs. Thus, user fees are not a panacea. In addition, user fees should not be a mechanism for deficit reduction.

The sixth question asks how the Agency can eliminate the backlogs in the review process.

- From our perspective, the AVMA can only encourage the examination of the applications with the ADAA and science-based decision making at the forefront of thought. Give thought to the future use of expert review panels.

Finally the Agency asks what other objectives should be included in the FDA plan?

- Third party payment for prescription drugs does not generally exist in veterinary medicine. The CVM should consider cost-effectiveness and the economic impact of its regulatory decisions on products and processes, specifically those related to evaluations of product efficacy and manufacturing requirements.

The AVMA's reply to the "CVM Specific" questions appear below:

1. Thinking about the many consumer protection functions performed by CVM, are there some that should be changed? If so, how? Are there some that could be deleted? Are there functions not included that you would add?

- We have examined the functions from a "relative outsider" perspective and do not recognize any changes that need to be made. The AVMA does not see major areas where the Center should be divesting itself of responsibility. Instead, we believe the Center should receive more dollars to support its responsibilities.

2. For which of these functions do you believe, it would be acceptable for CVM to charge fees?

- As mentioned, the AVMA supports user fees for new animal drug applications if such fees are directed toward enhanced review and approval of animal drug products. The economic reality of affordable drug prices continues to be part of the equation.

3. For which of these functions could, and should, CVM rely more on the efforts of third parties, such as testing laboratories, veterinary organizations, standards (domestic or international) setting organizations, states, or regulated industry?

- The AVMA supports the concept of third party involvement and would be happy to explore this issue with the CVM.

4. Which of these functions do you see as having the best potential for CVM to collaborate with its external stakeholders? Please be specific and name both the functions and the collaborating stakeholder.

- The CVM could collaborate with respect to many of its functions. Collaborating with those coalitions that focus on important issues, and involve multiple stakeholders cooperating in working groups, are ideal opportunities for the CVM. Examples would include the Coalition for Animal Health working for the ADAA, or the effort of those involved with medicated feeds to simplify and make uniform the Good Manufacturing Practices to be used by all types of feed facilities.

5. Which of these functions do you believe offers the greatest opportunities for CVM to place more emphasis on non-regulatory approaches -- such as education, technical assistance, and collaborative problem solving -- to protect and promote public health?

- Surveillance and Compliance would appear to be the functions that would benefit most from enhanced non-regulatory approaches. The AVMA encourages the Center to use organized veterinary medicine as a resource in the agency's decision making and a conduit for its message.

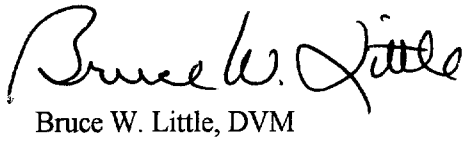
6. In the international arena, CVM is faced with similar questions on the allocation of its resources. Currently, the Center's international resources are split between international standard setting, such as the establishment of veterinary drug residue standards; efforts to internationally harmonize veterinary drug registration requirements; involvement in Agency efforts to develop mutual recognition agreements between the U.S. and other nations; offering technical assistance to foreign regulatory officials; and providing technical support to U.S. trade agencies. Would you maintain the current mix of effort, or change it? If you would change it, how?

- The AVMA is not aware of any need for change in the current mix. Multinational development of drugs is increasingly common. While energy devoted to the international arena does not result in

immediate gratification, such efforts are tremendously important to a long range vision of enhanced drug availability and should be a major goal of the Center.

The American Veterinary Medical Association thanks the CVM for this opportunity to comment and looks forward to ongoing cooperation with the Center. We thank the Center for recognizing the role of the veterinarian, as an informed professional, in the safe and effective administration of drugs to animals. Such recognition is apparent in the CVM's assignment of prescription or Veterinary Feed Directive status to drugs, creation of regulations for extralabel drug use, and application of professional flexible labeling. We look forward to continued responsible drug use in the care of animals, and hope the Center will keep the participation of our profession in mind as drugs are evaluated in the review process and monitored after marketing.

Sincerely,



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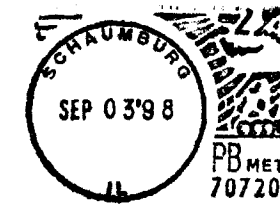

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